K080292
Page 1 of 2

510(k) Summary for Public Disclosure

Submitter:

St. Jude Medical
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JUL 25 2008

Contact:

Karen J. McKelvey
Principal Regulatory Compliance Engineer

Date Prepared:

February 1, 2008

Trade Name:

Epicor™ Medical Ablation Control System (ACS)
Epicor™ UltraCinch™ LP Ablation Device
Epicor™ UltraWand™ LP Tissue Ablation Wand
Epicor™ LP Positioning and Sizing (LP PAS™) System
Epicor™ LP Oblique Introducer
Epicor™ LP Connecting Cable

Common Name:

Ultrasonic Surgical Instrument

Classification Name:

System, Ablation, Ultrasound and Accessories

(21 CFR 878.4400)

Predicate Device:

Product	510(k) Number
Epicor Ablation Control System (ACS)	K022894
UltraCinch Tissue Ablation Device	K040641
UltraWand Ablation Device	K022894
UltraCinch Accessory Pack	K040641
UltraMaze Connecting Cable	K040641

Device Description:

The Epicor Ablation System is designed to deliver ultrasound energy to tissue in order to create an ablation lesion. Specifically, the system is intended for the ablation of cardiac tissue during cardiac surgery. The Ablation System consists of the Ablation Control System instrument, a reusable connecting cable, a family of sterile, disposable ablation devices, and accessories.

Epicor Ablation Control System Intended use:	The Epicor Medical Ablation Control System is intended for the ablation of cardiac tissue during cardiac surgery
UltraCinch LP Intended use:	The UltraCinch LP is intended for the ablation of cardiac tissue during cardiac surgery
UltraWand LP Intended use:	The UltraWand LP is intended for the ablation of cardiac tissue during cardiac surgery
LP PAS System Intended use:	The items in LP PAS System are part of the Epicor Cardiac Ablation System. The System is intended for the ablation of cardiac tissue during cardiac surgery
LP Oblique Introducer Intended use:	The LP Oblique Introducer is part of the Epicor Cardiac Ablation System. The System is intended for the ablation of cardiac tissue during cardiac surgery
LP Connecting Cable Intended use:	The LP Connecting Cable is part of the Epicor Cardiac Ablation System. The System is intended for the ablation of cardiac tissue during cardiac surgery
Technological Characteristics:	The new device has the same technological characteristics as the legally marketed predicate device.
Non-clinical Performance Data:	The changes made to the Epicor Ablation System underwent a battery of bench and user tests. Device validation testing was conducted in accordance with in-house procedures.
Conclusion:	An evaluation of the device changes indicates that the devices are as safe and effective as the previously marketed device to which they are being compared and do not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2008

St. Jude Medical
c/o Ms. Karen McKelvey
Principal Regulatory Compliance Engineer
1350 Energy Lane, Suite 110
St. Paul, MN 55108

Re: K080292
Trade Name: Epicor Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: OCL
Dated: July 14, 2008
Received: July 17, 2008

Dear Ms. McKelvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with

all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

9. Indications for Use

510(k) Number (if known): ~~N/A~~ K080292

Device Name: The Epicor™ Ablation System, including

- Epicor Medical Ablation Control System (ACS)
- Epicor™ UltraCinch™ LP Ablation Device
- Epicor™ UltraWand™ LP Tissue Ablation Wand
- Epicor™ LP Positioning and Sizing (LP PAS™) System
- Epicor™ LP Oblique Introducer
- Epicor™ LP Connecting Cable

Indications for Use:
The Epicor Medical Ablation Control System is intended for the ablation of cardiac tissue during cardiac surgery
Indications for Use:
The UltraCinch LP is intended for the ablation of cardiac tissue during cardiac surgery
Indications for Use:
The UltraWand LP is intended for the ablation of cardiac tissue during cardiac surgery
Indications for Use:
The items in LP PAS System are part of the Epicor Cardiac Ablation System. The System is intended for the ablation of cardiac tissue during cardiac surgery
Indications for Use:
The LP Oblique Introducer is part of the Epicor Cardiac Ablation System. The System is intended for the ablation of cardiac tissue during cardiac surgery
Indications for Use:
The LP Connecting Cable is part of the Epicor Cardiac Ablation System. The System is intended for the ablation of cardiac tissue during cardiac surgery

Prescription Use ☑ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080292